procedures and providing the requisite deference under Rule 52(a) of the Federal Rules of Civil Procedure.[4]

This Court's precedents make clear that the answer to this question is no. Matters of patent anticipation, like all matters of fact, must be reviewed in accordance with the constraints of Rule 52(a). For example, in *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986) (per curiam), this Court vacated the Federal Circuit's reversal of a district court's finding of

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[4] Rule 52(a) of the Federal Rules of Civil Procedure provides that, "[f]indings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses." Fed. R. Civ. P. Rule 52(a). The deference mandated by Rule 52 reflects "an accommodation of the respective institutional advantages of trial and appellate courts." *Salve Regina College v. Russell*, 499 U.S. 225, 233 (1991). This Court has specifically articulated the proper institutional role for an appellate court reviewing a district court's factual findings:

> In applying the clearly erroneous standard to the findings of a district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues de novo. The authority of an appellate court, when reviewing the findings of a judge as well as those of a jury, is circumscribed by the deference it must give to decisions of the trier of the fact, who is usually in a superior position to appraise and weigh the evidence. The question for the appellate court under Rule 52 (a) is not whether it would have made the findings the trial court did, but whether "on the entire evidence [it] is left with the definite and firm conviction that a mistake has been committed.

Zenith Corp. v. Hazeltine, 395 U.S. 100, 123 (1969) (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)). The standard of review requires the court to determine affirmatively that the district court's findings of fact were not supported by the evidence. *See Anderson v. Bessemer City*, 470 U.S. 564 (1985) ("Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.").

patent invalidity on obviousness grounds because the Federal Circuit did not explicitly find clear error. Just as this Court in *Dennison* required the Federal Circuit to apply Rule 52(a) when reviewing facts regarding the obviousness of a patent claim, this Court should also require the Federal Circuit to conform to Rule 52(a) when reviewing a district court's findings regarding anticipation.

In addition, in *Icicle Seafoods, Inc. v. Worthington*, 475 U.S. 709 (1986), this Court reversed the Ninth Circuit's attempt to review de novo the district court's determination that certain job activities qualified a group of on-board workers as "seamen" under 29 U.S.C. § 213(b)(6). As in this case, the Ninth Circuit purported to review the facts for clear error but "nowhere in its opinion did the [Ninth Circuit] ever mention any of the factual findings of the District Court, much less discuss or analyze them." *Id.* at 713. This Court rejected the Ninth Circuit's attempt to carve out a subject-dependant exception to Rule 52(a) and held that by relying on a factual finding not made by the district court, the Ninth Circuit failed to provide the deference mandated by Rule 52(a). *Id.* at 714. Rather than insert its own findings of fact, this Court explained that:

> If the Court of Appeals believed that the District Court had failed to make findings of fact essential to a proper resolution of the legal question, it should have remanded to the District Court to make those findings. If it was of the view that the findings of the District Court were "clearly erroneous" within the meaning of Rule 52(a), it could have set them aside on that basis. If it believed that the District Court's factual findings were unassailable, but that the proper rule of law was misapplied to those findings, it could have reversed the District Court's judgment. *But it should not simply have made factual findings on its own.*

Id. (emphasis added). *See also Amadeo v. Zant*, 486 U.S. 214 (1988) (reversing an Eleventh Circuit decision for failing to properly apply the clearly erroneous standard of review); *Anderson*, 470 U.S. at 580 (reversing a Fourth Circuit decision because the factual findings of the district court were not clearly erroneous); *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 858 (1982) (reversing a Second Circuit decision for "setting aside facts that were not clearly erroneous").

Like these prior cases, in this case the Federal Circuit also misconstrued the district court's findings of fact and inserted its own. As such, this Court's holdings in *Dennison* and *Icicle Seafoods* are directly on point, and the Federal Circuit ignored Supreme Court precedent by engaging in a de novo review of the facts. That reason alone justifies granting SmithKline's petition for certiorari as it is vitally important for the Courts of Appeals to follow established procedural law.

Dennison and *Icicle Seafoods* also demonstrate that Rule 52(a) does not allow for judicially created exceptions based on subject-matter, whether in the patent area or elsewhere, and this Court should grant SmithKline's petition to prevent the Federal Circuit from creating an exception to the clearly erroneous standard for anticipation determinations as well. Given the Federal Circuit's sole appellate jurisdiction over patent controversies, this Court should grant SmithKline's petition to prevent the misapplication of Rule 52(a) in patent controversies that remains otherwise unnoticed because of the unavailability of sister circuits to draw attention to problematic rulings.

B. The Federal Circuit's Erroneous Departure From The Settled Law Of Anticipation Invites Improper Fact-Finding And Requires Correction.

The requirements for patentability set forth in Section 102(b) of the Patent Code, upon which the Federal Circuit

based its decision, provide simply that a "person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." 35 U.S.C. § 102(b). As the plain language requires, this Court has long held that a challenger cannot invalidate a patent as anticipated without proving, clearly and convincingly, that the claimed invention was "described" in the prior art.

In *Tilghman v. Proctor,* 102 U.S. 707 (1881), the patent at issue claimed "the manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure." *Id.* at 709. Before the patented discovery, others had accidentally formed fat acids using the claimed process, but this Court held that such accidental production did not suffice to anticipate the patent: "We do not regard the accidental formation of fat acid . . . as any consequence in this inquiry . . . . Those engaged in the art . . . certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacture of such acids." *Id.* at 711.

The test for anticipation, this Court made clear, was a factual one – did the challenger show as a factual matter that the prior production was known and deliberate: "[i]f the acids were *accidentally and unwittingly produced,* whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery." *Id.* (emphasis added). This requirement was reinforced in *Eibel Process Co. v. Minnesota & Ontario Paper Co.,* 261 U.S. 45 (1923), where this Court again rejected a patent challenge for lack of proof that the prior art anticipated the invention knowingly and deliberately: "we find no evidence that any pitch of wire, used before Eibel, had brought such a

result as that sought by him, and in the second place, if it had done so under unusual conditions, *accidental results, not intended and not appreciated, do not constitute anticipation*." *Id.* at 66 (citing *Tilghman*, 102 U.S. at 711) (emphasis added).

The requirement of proof of deliberate and knowing anticipation is carried forward to the present day. In *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991) (Newman, J.), the Federal Circuit adopted the test for "inherent anticipation" outlined by this Court's decisions and its progeny: "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that [1] the missing descriptive matter is necessarily present in the thing described in the reference, and [2] *that it would be so recognized by persons of ordinary skill*." *Id.* at 1268 (emphasis added). Emphasizing the recognition prong, the Federal Circuit explained that "[t]his modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." *Id.* at 1269.[5]

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[5] The principle has also been applied repeatedly in the context of pharmaceutical patent cases. For example, after the antibiotic tetracycline was developed and patented, an accused infringer argued that the patent should be held invalid based on the purported presence of that antibiotic in trace amounts in the prior art Aureomycin antibiotic. The court rejected that attack, holding that "[t]he prior existence of tetracycline in trace amounts, unrecognized and of no use does not invalidate the patent." *Chas. Pfizer & Co. v. Barry-Martin Pharms., Inc.*, 241 F. Supp. 191, 194 (S.D. Fla. 1965) (citations omitted); *see also Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995)

The Federal Circuit decision here departs dramatically from these clear requirements for anticipation. The majority below held squarely that "anticipation *does not require a person of ordinary skill in the art to recognize* the inherent disclosure in the prior art at the time the prior art is created." App. 18a (emphasis added). As it was undisputed in the trial court record that no one recognized the existence of PHC hemihydrate at the time of the prior patent was issued in 1977, this departure from settled law allowed it simply to ignore the established facts. Indeed, the record is clear, and the trial court found, that PHC hemihydrate was unknown until it was discovered by SmithKline in 1985, shortly before the hemihydrate patent application was filed. The Federal Circuit's finding of anticipation is thus flatly inconsistent with this Court's precedents in *Tilghman* and *Eibel* as well as the Federal Circuit's own, now-overruled decision in *Continental Can*.

By discarding the requirement that alleged anticipation be proved, clearly and convincingly, to be knowing and deliberate, the Federal Circuit has unmoored anticipation from scientific fact. No longer is anticipation a factual inquiry concerning, in Judge Newman's words, what "technological facts are known to those in the field of the invention." *Continental Can*, 948 F.2d at 1269. Instead, under the Federal Circuit's decision, an accused infringer may now attempt to invalidate a patent by convincing a court that the prior art "naturally results" in production of the claimed subject matter at some indefinite time and in some unknowable amount – indeed, even if that production be unintentional and undetectable. This is not a meaningful factual inquiry, and, as the Federal Circuit's decision shows,

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(rejecting inherent anticipation attack on patent claiming a particular crystalline form of ranitidine hydrochloride, the active ingredient in Zantac®).

it invites the courts to invalidate patents without regard to the facts and without deference to the finder of facts.

Moreover, the Federal Circuit's new approach undermines the fundamental purpose of the Patent Code: "[t]o promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8. As this Court has observed, "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). That which is unrecognized in the prior art has not, by definition, been brought into the public domain through disclosure. It is only through investigation, and consequent disclosure through patenting, that the public can enjoy the new designs and technologies that exist unknown in the art. The Federal Circuit's ruling in this case of unwitting anticipation would deny the incentives of the Patent Code. Science and the useful arts are not advanced by precluding patents for the recognition of that which has long lain unknown.

The Federal Circuit's marked departure from the settled law of anticipation deserves correction. The court has plainly and deliberately departed from the law of anticipation, and done so in a way that allows it to ignore the detailed fact-finding of the trial court and the constraints of Rule 52(a). As the sole appellate court with jurisdiction over patent cases, it will never voluntarily relinquish the power it has now arrogated to itself to pass on the validity of issued patents, untethered by the record and the trial court's findings.

We expect the respondent, Apotex, will argue that the rule adopted by the Federal Circuit here is necessary to prevent a patentee from improperly using a later-filed patent to preclude practice of the prior art. However, whether an accused infringer is practicing the prior art and not the claimed invention is a factual question, and one not

supported by the findings of the trial court here. There is no suggestion in the trial court's findings that Apotex is in fact practicing the prior art, and, as discussed above, it is not even clear that the claimed PHC hemihydrate existed in the prior art, even in unrecognized form.[6] Indeed, as patent claims should ordinarily be construed to avoid claiming the prior art, such an argument by Apotex would be fundamentally misdirected and provides no warrant for distorting the law of anticipation as the Federal Circuit did here.

As Petitioners have argued, the Federal Circuit's decision casts a significant cloud on existing and future patents. Professor Donald Chisum, author of the leading patent law treatise, explains that the Federal Circuit's "broad" new doctrine of inherent anticipation "seems to allow a described process to anticipate every compound X that could result from that described process, based on later evidence that practicing the process produces at least a trace amount of X, whether or not X was relevant, expected, or detected." Donald Chisum & Michael Smith, "*SmithKline*: How the Expanding Inherent Anticipation Doctrine Affects Chemical

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[6] Moreover, whether or not Apotex is practicing the prior art so as to be outside the claims of a later-filed patent pertains to the issue of infringement, an issue on which PhRMA takes no position. The lack of findings regarding whether PHC hemihydrate existed in the prior art, however, distinguishes this case from another recent decision by the Federal Circuit on inherent anticipation, *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). In *Schering*, the Federal Circuit affirmed the district court's express finding that a particular, later-patented, active metabolite of a compound is necessarily produced when humans ingest that compound. *Id.* at 1381. As the earlier patent in that case claimed pharmaceutical use of an unidentified "active compound" produced upon ingestion, there was no issue in *Schering* whether the newly patented metabolite existed (albeit in uncharacterized form) in the prior art. *Id.* at 1376. In contrast, the district court in this case expressly refused to find that PHC hemihydrate existed in the prior art.

Patents," at 4, Apr. 8, 2005, http://www.mofo.com/docs/PDF/IPNewsletter0605.pdf. As a policy matter,

> it is not clear that a broad inherent anticipation rule is good: it places patentees in the uncomfortable position of not knowing whether their patents might be invalidated by a reference, perhaps not even closely related to their own research. For example, a patent on a new compound with pharmaceutical activity could be invalid if the compound was later shown to be a metabolite of some other drug, even if the other drug was used for a seemingly unrelated purpose.

Id. at 5. "Such heightened uncertainty," Professor Chisum concludes, "reduces incentives for research and for disclosure in the form of patents." *Id.*

In short, the holding below violates not just the requirements of section 102 of the Patent Code and Rule 52(a) of the Federal Rules of Civil Procedure, but equally the essential working assumptions of a fair regime for the promotion and protection of innovation and intellectual property. This Court's intervention is therefore warranted.

CONCLUSION

For these reasons, the petition should be granted.

Respectfully submitted,

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Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,
Petitioners,

v.

APOTEX CORP., APOTEX, INC., AND TORPHARM, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioners. Counsel for Petitioners has consented to the filing of this brief. WLF was unable to obtain the consent of Counsel for Respondents, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF devotes a substantial

portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared before this Court and other federal courts in numerous cases raising important regarding the scope and validity of pharmaceutical patents. *See, e.g., Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.* 359 F.3d 1361 (Fed. Cir. 2004) (scope of patent protection); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir.) (scope of causes of action under 35 U.S.C. § 271(e)(2)), *cert. denied*, 540 U.S. 1048 (2003); *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (Hatch-Waxman Act procedures for resolving drug patent disputes), *cert. denied*, 537 U.S. 941 (2002). WLF also filed briefs in this case in support of Petitioners when the case was before the U.S. Court of Appeals for the Federal Circuit.

WLF fully supports Petitioners' request that the Court grant review in this case. WLF writes separately in order to emphasize its particular concern over the practical impact of the Federal Circuit's decision. The decision below and similar recent decisions of the Federal Circuit have had the effect of writing the "accidental anticipation" doctrine out of the patent law, thereby significantly decreasing the availability of patent protection for new and useful products and processes. WLF is concerned that the novel rule announced by the Federal Circuit in this case and *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 348 F.3d 992 (Fed. Cir. 2003), will undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights, and thus reduce incentives for companies to invest in new, life-saving therapies.

WLF is filing this brief because of its interest in promoting the welfare of the health care industry and the public at large; it has no direct interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct

economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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November 16, 2005

QUESTION PRESENTED

Whether the Federal Circuit erred in holding, in conflict with this Court's decision in *Tilghman v. Proctor*, 102 U.S. 7007 (1881), and its progeny, that the "unwitting" and "unappreciated" prior creation of a product renders a subsequent patent of that product invalid as "inherently anticipated" and thus not novel under Section 102 of the Patent Act.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

STATEMENT OF THE CASE

The Federal Circuit invoked the doctrine of "inherent anticipation" to invalidate a patent issued to Petitioners for crystalline paroxetine hydrochloride hemihydrate ("PHC hemihydrate"). The appeals held that an earlier patent (the "Ferrosan patent") "inherently" discloses PHC hemihydrate even though it does not do so literally, and thus that Claim 1 of Petitioners' patent is invalid as inherently anticipated under 35 U.S.C. § 102(b).[2] That ruling is consistent with recent Federal Circuit decisions that have steadily expanded the scope of the inherent anticipation doctrine. Under that doctrine, a patent can be deemed invalid based on the existence of prior art in which all the characteristics of the claimed invention are *inherently* present, even though the prior art may not affirmatively disclose those characteristics. *See, e.g., Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 348 F.3d 992 (Fed. Cir. 2003). The appeals court invalidated the SmithKline Beecham patent without once mentioning the "accidental anticipation" or "accidental prior use" doctrine, which holds that inherent anticipation is inapplicable where, even though a process or product may be inherent in the prior art, the process or product is not appreciated by the inventor or anyone else. Nor did the appeals court cite any of this Court's decisions from which the accidental prior use doctrine derives.

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[2] The Federal Circuit referred to the two relevant patents as the "'723 patent" and the "'196 patent," a reference to the numbers assigned to the patents by the patent office. For ease of understanding, WLF adopts the names employed in the Petition: Petitioners' patent is referred to herein as the "SmithKline Beecham patent" or the "hemihydrate patent," and the earlier patent is referred to as the "Ferrosan patent," a reference to the European company that obtained the earlier patent.

In the 1970s, scientists at the Danish company A/S Ferrosan ("Ferrosan") invented a new class of chemical compounds, including a compound that became known as paroxetine. In 1977, it obtained the Ferrosan patent on those compounds. Lacking the financial resources necessary to develop its invention commercially, Ferrosan later licensed its paroxetine technology to Petitioners and provided them with the results of its research – including its methodology for synthesizing a crystalline hydrochloride salt of paroxetine, or paroxetine hydrochloride (PHC). Ferrosan's methodology described the synthesis of an *anhydrous* form of PHC, meaning that it contains no water molecules in its crystal structure.

Scientists employed by Petitioners (collectively, "SmithKline") then spent several years working to improve the process for the manufacture of paroxetine and PHC. It was not until 1985 that a SmithKline scientist discovered a new crystalline form of PHC. This new crystalline form, PHC *hemihydrate*, contains one water molecule for every two molecules of paroxetine hydrochloride bound in the crystal. SmithKline obtained a patent on PHC hemihydrate in 1988, and determined that it would seek authority from the Food and Drug Administration (FDA) to market it as an antidepressant. That approval did not come until 1993, when SmithKline began marketing Paxil as an antidepressant, with PHC hemihydrate as its active ingredient. In the meantime, the Ferrosan patent had expired in 1992, one year before marketing of Paxil began.

SmithKline filed this patent infringement action in 1998, claiming that the PHC antidepressant drug that Respondents (collectively, "Apotex") proposed to market violated the hemihydrate patent. Apotex defended by claiming both patent invalidity and that its proposed marketing would not infringe